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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,555	02/25/2002	Michael G. Goggins	JHU1700-1	7972

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EXAMINER

WILDER, CYNTHIA B

ART UNIT PAPER NUMBER

1637

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/084,555

Applicant(s)

GOGGINS et al.

Examiner

Cynthia B Wilder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Feb 3, 2003

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☒ Claims 1-21 are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restriction*

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6, 20 and 21 drawn to isolated nucleic acid, classified in class 435, subclass 23.1.
  - II. Claims 7-15, drawn to a method for detecting a cellular proliferative disorder, classified in class 435, subclass 6.
  - III. Claims 16-19, drawn to a kit, classified in class 435, subclass 810.

### *Sequence Election Requirement Applicable to All Groups*

In addition, each Group detailed above reads on patentably distinct sequences, SEQ ID Numbers (SEQ ID NO:). Each sequence is patentably distinct because the sequence are structurally unrelated sequences and a further restriction is applied to each Group. Applicant must further elect a single SEQ ID NO: (See MPEP 803.04). Applicant must specifically identify each of the corresponding SEQ ID NO: X or SEQ ID NO: Y for the sequence elected. Applicant is to elect **one** (*single*) SEQ ID NO: selected from SEQ ID NOS: 1-42 and one primer pair (**two** SEQ ID NOS:) selected from 43-105 for prosecution on the merit along with the elected group. It is noted that the elected single SEQ ID NO: or primer pair must correspond with the claims of the elected group. For example, if the Group I is elected, then one SEQ ID NO: must be elected from the group consisting of SEQ ID NO: 1-42 and one primer pair (two additional sequences) must be elected from the group

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consisting of SEQ ID NOS: 43-105 whereas if the group II is elected, then one SEQ ID NO: from the group consisting of SEQ ID NOS: 39-42 must also be elected, respectively.

**Applicant is advised that examination will be restricted to only the elected SEQ ID NO: and corresponding claims and should not be construed as a species election.**

2. The inventions are distinct, each from the other because of the following reasons: ~~Inventions~~ I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are patentably distinct requiring different fields of search. For example, the product of invention I is drawn to an isolated nucleic acid and primer that can be used in methods of hybridization and amplification for detecting a target sequence of interest whereas the product of invention III comprises carriers, primers, enzymes and modifying agents that can be used in methods of forensic analyses or in primer extension reactions for the detecting a mutation or variation in a sequence on in methods of sequencing.

3. Inventions I, III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product comprising the isolated nucleic acid sequence of Invention I and the kit of invention III can be used in a materially different process besides in a method for detecting

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cellular proliferative disorders. For example the isolated sequence and kit can be used in methods of site-directed mutagenesis or in methods of forensic analysis or in methods of detecting a pathogen. The different inventions are patentably distinct requiring different fields of search.

4. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

***Species Election***

5. This application contains claims directed to the following patentably distinct species of the claimed invention: Genes selected from MICP1-42 of Table 1 at page 49 of the specification.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (**one gene from the TABLE 1A**) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

#### ***Contact Information***

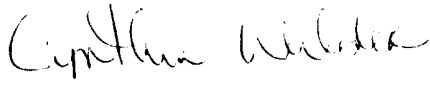
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Group's receptionist at (703) 308-0196.

cbw  
April 17, 2003

  
Cynthia B. Wilder, Ph.D.  
Patent Examiner  
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